In the Specification:

Amend the specification by inserting before the first line the sentence: "This application is a division of application number 09/859,555, filed May 17, 2001, (pending), which is hereby incorporated by reference herein."

Please rewrite the paragraph beginning at page 22 line 19 to read as follows:

With lockable mechanism 222 in a closed position and the proximal end of the coiled structure expanded, the physician selects a wire guide 239, as shown in FIG. 3, having a diameter less than the diameter of the lead passageway. The physician determines the passageway by inserting the wire guide therein and sensing for any blockages. The guide includes a control mechanism such as a knurled cylindrical chuck 240 positionable about the proximal end thereof. The physician grasps the knob to extend the guide into the lead passageway and to rotate the guide back and forth to clear or break through any blockages caused by tissue or occluding material. The guide is also used to determine or size the inside diameter of a second coiled structure that may be coaxially positioned inside coiled structure 211. When utilized as a control mechanism for stylet wire 200, the chuck may also include appendages 260 for rotating and counting the number of times the stylet wire is rotated. Having determined the lead passageway with the wire guide, several other guides similar to guide 239 are individually inserted in the passageway to determine the actual inside diameter at the proximal end. Guide 239 is also utilized to determine if coiled structure 211 has been deformed or damaged and to determine the smallest diameter of the coiled structure and passageway.

Please rewrite the paragraph beginning at page 25 line 29 to read as follows:

Depicted in FIGS. 29 and 30 is illustrative removal apparatus 2901, which represents an enhancement to apparatus 2801 of FIG. 28. Removal apparatus 2901 includes stylet wire 2902 of commercially available .021" diameter stainless steel wire having tapered portion 2903, flat portion 2904, and distal end 2905. Removal apparatus 2901 further includes wire coil 2906 having a central plurality of wire turns 2907, a distal plurality of wire turns ~~2908~~ 2909~~, and a proximal plurality of wire turns 2910~~. Wire coil 2906 also includes a somewhat straight portion ~~2909~~ 2908 extending longitudinally between the central and distal pluralities. Distal plurality ~~2908~~ 2909 is closely spaced, much less than the central plurality, and fixedly attached with tin-silver solder ~~2911~~ 2910 about the distal end of the stylet wire next to silver solder bead ~~2912~~

2911. As shown in the top view of FIG. 30, tapered portion 2903 and flat portion 2904 of the stylet wire is positioned between the distal and central pluralities of wire turns and has a maximum width of .030" that approximates the width of the passageway of the implanted lead. Straight portion ~~2909~~ 2908 of the wire coil extends longitudinally from the central plurality along stylet wire 2902 where the diameter of the stylet wire is uniform. Straight portion ~~2909~~ 2908 further extends longitudinally along tapered portion 2903, which has a 30 degree tapered edge, and flat portion 2904, which has an edge parallel the stylet wire. Tapered portion 2903 and flat portion 2904 are each approximately .15" long.

Please rewrite the paragraph beginning at page 26 line 20 to read as follows:

As depicted in FIG. 31, removal apparatus 2901 is positioned in passageway 3001 and secured to coiled structure 3002 of implanted pacemaker lead 3003. Stylet wire 2902 has been rotated in a counter-clockwise direction to wrap straight coil portion ~~2909~~ 2908 around tapered stylet portion 2903. The wrapped straight coil portion engages the coiled structure of the lead and secures the stylet wire to the implanted lead. As the straight coil portion is wrapped around the tapered stylet portion, turns of the central plurality move distally to expand and engage the tapered stylet portion and the coiled structure of the implanted lead.

Please rewrite the paragraph beginning at page 31 line 17 to read as follows:

As depicted in FIG. 18, removal apparatus 1801 includes wire guide 1802 that is inserted into the passageway of the elongated structure. Control tube 1803 includes two longitudinal passageways 1804 and 1805. Passageway 1804 receives the wire guide as the control tube is inserted into the passageway of the elongated structure. Positioned at the distal end of the control tube is inflatable balloon ~~806~~ 1806 with passageway 1805 leading thereto through sideport or aperture 1807. To secure the control tube to the elongated structure, a fluid is passed through passageway 1805 to inflate the balloon to an expanded position.

Please rewrite the paragraph beginning at page 33 line 26 to read as follows:

Depicted in FIG. ~~4 is fibrotic tissue 209 encapsulating heart lead 204 in blood vessel 216.~~ 3 is fibrotic tissue 218 encapsulating heart lead 204. When this occurs in small diameter veins where blood flow has been restricted or prevented, separation and removal of the lead from the

tissue is difficult and often causes severe damage or destruction to the vein. Without tension on stylet wire 200, separation is usually not possible in these situations.

Please rewrite the paragraph beginning at page 34 line 3 to read as follows:

As shown, the distal end of the Teflon separator tube 212 is beveled and includes a cutting edge or edge having a number of teeth for separating heart lead insulating material 201 from encapsulating fibrotic tissue 209. As depicted in FIG. 7, hollow separator tube 212 has a metal beveled tip 242 attached to the distal end thereof with, for example, by a medical grade adhesive. The metal tip provides a more durable edge for separating or cutting encapsulating fibrotic tissue from the lead.

Please rewrite the paragraph beginning at page 43 line 21 to read as follows:

FIG. 40 depicts an embodiment of the locking stylet 510 in which the expandable portion 513 comprises a multifilar wire bundle 515 that comprises a series of adjacent windings 570 helically wrapped around the style 511 and affixed thereto. In the illustrative embodiment, the multifilar wire bundle 515 includes six individual expandable members 514 that comprise helically wound metal wires; however any practical number of wires can be used. It has been found that using a multifilar wire bundle 515, rather than a single helically wound wire, allows for greater expansion. This results in having a .015" OD locking stylet that can expand to a sufficient diameter to engage and remove the complete array of standard pacemaker leads where the range of coil lumen diameters is typically .016" to .032" (approximately 0.4 to 0.9 mm). The term 'engage' as used within the portion of the specification describing the embodiments shown in FIGs. 40-47, is defined as a situation in which the expandable members 514 displace, shift, or otherwise intersperse with selected ones of the pacemaker lead coils 548 in manner that forms a locking interaction or biting engagment. This contrasts with certain prior art devices in which the interaction between the lead removal apparatus and the pacemaker coils is primarily a frictional relationship. As shown in FIG. 41, one method of forming the multifilar wire bundle 515 is to helically wind the six individual wires 514 together over a pin 541 in the configuration that will ultimately be attached distally to the stylet 511. The individual wires 514 can be soldered together, if so desired, at their proximal end, which in that case, the pin 541 should be made of titanium or nitinol such that the solder will not stick. Once helically wound, the

multifilar wire bundle 515 is inserted over the stylet 511 as shown in FIG. 40. The expandable portion 513 comprising the multifilar wire bundle 515 of the illustrative embodiment is divided into three main sections. The distal section 517 includes a relatively tight wound wrapping of a multifilar wire bundle 515 that is affixed to the stylet 511 about the distal end 516 of the locking stylet 510 with a distal fixation joint 520 such as a solder joint, a crimped band, or some other well-known attachment of fixation means. In the intermediate section 518, the multifilar wire bundle 515 of the illustrative embodiment is wound more loosely (i.e., with a greater pitch) to permit greater expansion during deployment. While the individual wires 514 of the multifilar wire bundle 515 are kept tightly together within the bundle, the gaps 553 between the windings 570 of adjacent multifilar wire bundles 515 increase over that of the distal section 517, in which the gaps 553 are generally minimal (e.g., 0.0035") to nonexistent. The pitch 557 of an individually wound wire 514 can vary within the immediate section 518, depending on a number of parameters (number of wires, wire diameter, etc.) and the range of expansion desired. In the illustrative embodiment with an approximately 3" (7.6 cm) expandable portion that includes a six-wire bundle 515 of 0.004" stainless steel wire, the multifilar wire bundles 515, which measures approximately 0.024" in width, include an increasing pitch 557 toward the center 554 of the intermediate section 518, with a maximum pitch 557 of approximately 0.12". The gaps 553 between the mutlifilar wire bundles 516 become progressively narrower in width toward the proximal half of the intermediate section 518. In the proximal section 519 of the illustrative embodiment, the windings 570 of the mutifilar wire bundle 514 include gaps 553 that essentially disappear such that the individual bundles 515 are not readily discernable. These dimensions are merely exemplary and can be varied according to the various structural parameters selected and the desired performance characteristics of the lead extraction apparatus 510. At the proximal end 545 of the expandable portion 513, a proximal fixation joint 521, such as a silver solder joint or other bonding means, may be included, however, it is not essential or necessary for the expandable portion 513 to properly function. Unlike the distal fixation joint 521, only the individual wires 514 are soldered together in a proximal fixation joint 521, leaving the expandable portion 513 free to slide over the stylet 511 at that point. An optional ring, section of cannula, or other structure can be attached to the proximal end 545 of the expandable portion 513 to provide a surface against which the actuator portion 512 may contact.

Please rewrite the paragraph beginning at page 49 line 16 to read as follows:

FIGs. 42-43 depict embodiments related to that of FIG. 40. In the embodiment of FIG. 42, the expandable portion 513, comprises ~~expandable members~~ wires 514 that include a plurality 544 of substantially parallel wires that are affixed both distally and proximally with fixation joints 520,521, such as silver solder. The individual wires 514 bow outward as the expandable portion 513 is compressed by the advancement of the actuator portion 512, thereby providing an radial expansile force, whereby the expandable ~~members 14~~ wires 514 engage the coils of the pacemaker lead. As with the embodiment of FIG. 40, the ~~wire~~ wires 514 ~~is~~ are typically annealed, such that ~~it~~ they can easily deform to allow the expandable ~~member~~ portion 513 to compress. Alternatively, the wires 514 can be formed with slight kinks or scores within the surface thereof, to facilitate bending during deployment.

Please rewrite the paragraph beginning at page 49 line 28 to read as follows:

The expandable portion 513 depicted in FIG. 43 includes a cannula that includes a series of longitudinal slots 543 that form a like number of expandable members ~~514~~ 542. As with the embodiments of FIGs. 40 and 42, compression of the expandable member 513 results in deformation of the expandable members ~~514~~ 542 which in turn, contact and engage with the coils of the pacemaker lead to permit its removal from the patient. In addition to having parallel slots 543 as shown, the slots 543 could be of a helical or spiraled configuration. A second inner cannula could be used in conjunction with the first cannula, the second having a different configuration of slots to compliment or enhance the function of the first cannula. It is also possible to combine wound wire with a cannula to form the expandable portion 513. It is possible to conceive of an almost unlimited number of different configurations of the expandable portion 513 that would allow a series of expandable members 544 to be compressed via an actuator portion 512 and plastically or elastically deformed outwardly to engage the coils of an ensnared lead, thereby assisting in its removal from body tissue. Any such embodiment should be considered to fall within the scope of the current invention.

Please rewrite the paragraph beginning at page 50 line 16 to read as follows:

FIG. 44 depicts the locking stylet 511 of FIG. 40 following deployment within a pacemaker lead 546. As the actuator portion 512 is advanced through the coils 548 of the

pacemaker lead 546, over the stylet 511, it contacts the proximal edge 545 of the expandable portion 513. Further advancement of the actuator portion 512 forces the expandable portion 513 to become longitudinally compressed. As the expandable portion 513 becomes longitudinally compressed, one or more of the individual wires 514 comprising the expandable portion 513 will 'pop out' or kink and extend outward from the mulitfilar bundle 515 and stylet 511 as longitudinal force is applied. As the gaps 553 between the helical windings 570 narrow and addition wires 514 deform outward, the expandable portion 513 is compressed further. In a larger sized pacemaker lead, for example, the expandable portion 513 may be compressed in length from 3" down to about 0.5". This causes the unsecured expandable members 544 of the intermediate section 518 to unwind as they plastically deform, thereby expanding outward to contact the coils 548 and push them outward against the outer insulation 547 of the pacemaker lead 546. The expansile force of the expandable members 544 often results in the individual wires being ~~pressure~~ pressed into, and some cases, through the spaces 550 between the coil turns, thereby increasing the fixation between locking stylet 510 and the pacemaker lead 546. Generally, mere frictional engagement between the device 10 and coils 548 is not sufficient to allow the lead to be removed from the patient since the force required typically cannot be achieved before the frictional engagement fails. The fact that the coils 548 themselves are typically multifilar, acts to improve the fixation, compared to an lead embodiment having a single coiled electrode wire. As depicted, a section 565 of four multifilar coils 548 is generally shifted outward as group, as the wires 514 of the expandable portion apply sufficient force that particular section 565. The adjacent section 566, which is not being impinged by the expanding wires 514, remains in its original position, thereby creating a 'shoulder' at the junction 569 between the two adjacent sections 565,566, this shoulder facilitating positive fixation of the lead when traction is applied. The actuator portion 512 is advanced until resistance is met from the expandable portion 513 being unable to further compress. Depending on the size of the coil lumen 551 and the number of wires 512 in the multifilar wire bundle 515, the expandable members 544 can compress and deform both outward and inward to form at least one irregular-shaped expanded mass 549 of deformed wires. If the device 510 is being deployed in a smaller lumen pacemaker lead 546, e.g., 0.016", it requires fewer wires 514 deforming outward to successfully engage the coils 548 and in fact, a large expanded mass 549 which is generally required for engaging larger lumen leads, would not have an opportunity to form given the space

limitations. The random and irregular geometry of the protruding wires 514 that eventually comprise the expanded mass 549 with its twisted bends and interlocking wires, improves fixation compared to expandable members 544 with regular curved geometries. The multifilar wire bundle 515 also acts to increase the mass needed to fill larger coil lumens which may have up to 4 times the cross-sectional area, thereby permitting one size of locking stylet 510 to work for both smaller and larger size coils. The shape of the expandable mass 549 can vary widely, depending on how it is formed and deployed. For example, in smaller diameter coil lumens 551, the expandable portion 513 may form more than one smaller expanded mass 549, rather than one large one. It should be noted that hand winding of the mutifilar wire bundles 515 adds to irregularity of the expanded mass 549 shape over that which would result from the bundles being machine wound.

Please rewrite the paragraph beginning at page 52 line 11 to read as follows:

FIG. 46 depicts an embodiment in which the proximal handle ~~23~~ 523 includes an elongated proximal portion 524 in a pre-shaped or preformed first configuration 561 which represents the relaxed state of the proximal portion 524. In the illustrative embodiment, the first configuration 561 is preformed such that the intertwined wire 556 comprises a compacted arrangement, such as the illustrative plurality of coiled loops 562 (*e.g.*, 3-4). The illustrative first configuration 561 conveniently provides the operator an improved configuration for gripping the apparatus 510, such as through the aperture 571 formed by the loops 562, and more importantly, to be able to maintain the proximal portion 524 in a more compact and manageable configuration to reduce the likelihood of a portion thereof passing beyond the outer edge 564 of sterile field 563. Without the compact, pre-shaped configuration 561, a second person is typically required to hold and maintain the proximal portion 524 within the sterile field 563. As noted, the proximal portion 524 is made particularly long, in part, to permit the operator to manipulate or uncoil the proximal portion 524 into a second configuration 567 (depicted in FIG. 40) which is sufficiently straight to allow a medical device (not shown) having a passageway, such as a dilator sheath, to be fed thereover, usually for purposes of assisting in the loosening of scar tissue along the lead path. The proximal portion 524 can either be constrained by operator into the second configuration 567, or it can be done so by feeding the sheath or other medical device over the proximal portion 524. The first configuration 561, as used herein, represents a compacted configuration that includes an overall diameter in its widest plane, including any coils, turns, and

bends, that exceeds the passageway diameter of a standard medical device, such as a dilator sheath. The second configuration ~~267~~ 567, as used herein, includes a sufficiently straight configuration (not necessarily being substantially straight) such that a standard medical device, such as a dilator sheath, can be advanced over the proximal portion without a large degree of difficulty.

Amend the paragraph beginning on page 53 line 11 as follows:

In the embodiment of FIG. 40, the second configuration ~~267~~ 567 may represent the relaxed state, in contrast to the embodiment of FIG. 46, which requires manipulation by the operator, to attain a substantially straightened configuration. Preferably, but not essentially, the proximal portion 524 is designed such that once the medical device has passed thereover, the proximal portion 524 tends to resiliently return substantially to the first, compacted configuration 561, although it is typical that a certain amount of plastic deformation occurs such that the original shape is not attained. By adding shape memory to the proximal portion 524 by winding the intertwined wire 556 around a fixture to form a series of coiled loops 562, the operator can conveniently unwind the proximal portion 524 in a controlled manner and without assistance as the sheath is fed and advanced over the proximal end 533 of the apparatus 510. It is particularly advantageous to have the proximal end 533 of the apparatus in relative proximity to the point at which the operator grasps the apparatus 510, as opposed to having to feed the sheath over the proximal end 533 of an uncoiled proximal portion 524 that can be 50-60 cm or more away, something that at best, is difficult to do without allowing a portion of the proximal portion 524 to inadvertently leave the sterile field 563 or contact a non-sterile surface. While the pre-shaped configuration 561 of the illustrative embodiment, comprising coiled loops 562, represents one preferred embodiment, it should be noted that other pre-formed shapes (*e.g.*, a serpentine configuration) can be fashioned in order to achieve the desired goal, reducing the proximal portion 524 to a manageable configuration that can be manipulated by a single operation. Additional components may also be included, such as clips, housings, etc.) which cooperate with the proximal portion 524 to achieve a compact state, and that still permit passage of a sheath thereover. Not only does the pre-shaped or coiled proximal portion 524 of the handle 523 have utility in each of the illustrative embodiments, conceivably, any apparatus constructed for removing elongated structures, such as pacemaker and defibrillator leads, catheters, and the like, can be modified to include a compacted or pre-shaped elongated handle which can function for

any of the purposes described above. As used herein, the proximal handle 523 is a common element of all lead extraction devices that are manually manipulated by an operator, with the proximal portion 524 being a component thereof for purposes of nomenclature. The illustrative proximal handle 523 is exemplary, and it should be noted that the proximal handle 523 and proximal portion 524 may represent a common element in some embodiments, especially if the coiled configuration 561 is used as the sole means by which the operator grips and applies traction to the apparatus 510. Additionally, the distal handle 522 of the illustrative embodiments of FIGS. 40-47 is not necessarily present in all embodiments that utilize the coiled configuration of the proximal handle 523 and proximal portion 524, particularly those which lack an actuator portion 512.